510(k) summary

K020645

21 CFR 807.92

Date: 02/18/02

Official Contact: Donald E. Dalton

MAR 15 2002

Manufacturer: BioHorizons Implant Systems, Inc.
One Perimeter Park South
Suite 230 South
Birmingham, AL 35243
Phone: (205) 967-7880
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Proprietary Name

The Maestro System™

Common Name

Screw-type Dental Implant

Classification Name

Endosseous implants, surgical components, and prosthetic attachments

Predicate Device

The predicate device is The Maestro System ™, a screw-type dental implant manufactured and distributed by BioHorizons Implant Systems Inc. Authorization to legally market the predicate BioHorizons Maestro System implant has been documented under the following 510(k) numbers: K010458, K960026, K964330, K972313, K010458, K020133.

Device Description

The proposed Maestro System screw-type dental implant is a machined titanium, screw-form implant supplied in diameters of 4.0 mm and 5.0 mm, and in active thread area lengths of 9 mm, 12 mm, and 15 mm. The implant will have a polished collar length of 2 mm. The implant raw material is titanium alloy as specified in ASTM F136 – Specification for Wrought Titanium 6AL-4V ELI Alloy for Surgical Implant Applications.

The device is further processed by treating the surface with resorbable blast media (RBM) or coating with synthetic hydroxylapatite (HA). The product is packaged using materials known in the industry to be appropriate for medical device packaging and will be provided sterile, validated in compliance to ANSI/AAMI/ISO 11137, Sterilization of

healthcare products – Requirements for validation and routine control - Radiation Sterilization, with a minimum sterility assurance level of 10^{-6}.

The Maestro System ™ is a comprehensive system containing implants, surgical components, and prosthetic components. The implants are specifically designed to optimize strain distribution to contiguous bone under functional loading in order to promote strain-induced bone growth and interface maintenance over the long term. This is achieved by optimizing implant designs based on bone quality.

The following table provides a comprehensive summary of the implant sizes for which authorization to market has been received.

Diameter	Design	Length (mm)	Coating
ϕ3.5	D2	9,12	RBM
	D3	9,12,15	RBM
	D3	9,13	TPS
ϕ4.0	D1	9,11,13	RBM
	D2	9,12,15	RBM/HA
	D3	9,12,14	TPS
	D3	9,12,15	RBM/HA
	D4	9,12,13,15	HA
ϕ5.0	D1	9,11	RBM
	D2	9,10,12,15	RBM
	D3	9,11,13	TPS
	D3	9,12,15	RBM/HA
	D4	9,12,14,15	HA

Table. Previously cleared implant size (RBM = Resorbable Blast Media Surface; TPS = Titanium Plasma Spray Coating; HA = Hydroxylapatite Coating).

Following five years of clinical use, this submission proposes offering an additional polished collar length and threaded area length to assist the dental practitioner in treatment planning and ease of use with the product. Three base implant designs, corresponding to each bone density classification (D1/D2, D3 and D4) will be available in 4.0 mm and 5.0 mm diameters. Each implant design, manufactured from titanium alloy conforming to ASTM F 136, will be available in three lengths and may feature a Resorbable Blast Media (RBM) surface treatment, or hydroxylapatite (HA) coating. The following table provides a comprehensive summary of the proposed implant sizes which will include the changes.

Diameter	Design	Length (mm)	Coating
ϕ4.0	D3	9, 12, 15	RBM, HA
ϕ5.0	D3	9, 12, 15	RBM, HA

Intended Use

The Maestro System™ may be used in the mandible and maxilla for use as an artificial root structure for single tooth replacement or as abutments for fixed bridgework and dental retention. The Indication/Intended use of the modified device, the Maestro System™, as described in its labeling has not changed.

Technological Characteristics

The Fundamental Scientific Technology of the modified device has not changed. The only change has been to increase the polished collar length to 2 mm. The overall length of the implant will remain unchanged. All materials, suppliers, processing, packaging and sterilization methods remain the same. The proposed Maestro System ™ dental implant is substantially equivalent to all features of the predicate devices which could affect safety or effectiveness due to the similarities in design, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2002

Mr. Donald E. Dalton
Director, Quality Assurance
BioHorizons Implants Systems, Incorporated
One Perimeter Park South, Suite 200 South
Birmingham, Alabama 35243

Re: K020645
Trade/Device Name: The Maestro System™
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: February 28, 2002
Received: February 28, 2002

Dear Mr. Dalton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020645

510(k) Number (if known): _____

Device Name: The Maestro System™

Indications for Use:

The Maestro System™ may be used in the mandible and maxilla for use as an artificial root structure for single tooth replacement or as abutments for fixed bridgework and denture retention.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____
(per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020645